REMARKS

Status of the Claims

Claims 1-104 are pending in the application. Claims 1-72 were withdrawn pursuant to an election requirement. Thus, claims 73-104 are presented for examination.

Rejection Under 35 U.S.C. § 102(a) – Solomon et al.

Claims 73-74, 84, 95, 97 and 103 are rejected under 35 U.S.C. § 102(a) as being anticipated by Solomon et al. (U.S. Pat. No. 6,261,271). Applicant respectfully traverses this rejection.

Solomon et al. does not teach the invention of the claims. Specifically, Applicant states that the rejection over Solomon et al. has been rendered moot by the previous amendment to independent claim 1. Solomon et al. fails to teach all of the elements of the present invention as claimed in amended independent claim 73, which is directed to

> ...a first ***annular layer comprising a matrix polymer, an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor that form a single distinct matrix polymer region***, a first polymeric barrier layer at least partially covering an interior surface of said first annular layer and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer. (emphasis added).

The Solomon et al. reference fails as an anticipatory reference because it does not disclose ***all*** of the features of the claimed invention. Specifically, Solomon et al. fails to teach an annular layer that contains ***all three components***: matrix polymer, the antimicrobial agent, and a microbial attachment/biofilm synthesis inhibitor to form a ***single distinct matrix polymer region***. Solomon et al. fails to teach an annular layer that contains all three components within that layer to form one distinct matrix polymer region.

When Solomon et al. speaks of a polymer having a "dual anti-infective activity," it is not speaking of dual agents in a ***single distinct matrix polymer region***. Rather, the "dual" activity is achieved by putting an anti-infective in ***two separate layers***—a bulk layer and a surface coating layer. For example, Solomon et al. states that "[t]he preferred catheter of the invention includes a polymer having both bulk distributed chlorhexidine and a chlorhexidine coating. This embodiment of the invention produces a dual anti-infective activity. The surface coating provides a readily available and rapid release of chlorhexidine. The bulk distributed chlorhexidine, due to the hydrophilic nature of the polymer, migrates slowly to the surface when

the catheter is in contact with a body fluid and produces anti-infective activity of long duration." (Solomon et al., col. 6, lines 23-32). Nowhere does Solomon et al. teach a single polymeric matrix region containing ***both*** an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor. Thus, Solomon et al. fails to teach an element of the claimed invention and fails to anticipate claim 1.

Solomon et al. suffers from a second fundamental deficiency. It fails to teach a "microbial attachment/biofilm synthesis inhibitor." The Examiner mistakenly states that "chlorhexidine [is] one of the same materials currently disclosed for this purpose." This statement is factually erroneous. As would be appreciated by one of skill in the art, chlorhexidine is not a microbial attachment/biofilm synthesis inhibitor. Chlorhexidine is correctly identified in Applicant's specification as an "antimicrobial agent" (*see* paragraph [0038] of Applicant's specification). Examples of microbial attachment/biofilm synthesis inhibitors are provided in paragraph [0039] of the Applicant's specification. Chlorhexidine is ***not*** listed anywhere as a microbial attachment/biofilm synthesis inhibitor. Solomon et al. as well states that chlorhexidine is an antimicrobial. See Example V ("The antimicrobial-containing [chlorhexidine-containing] tubings of Example I..."). There is simply no evidence to support the Examiner's assertion that the chlorhexidine of Solomon et al. is one of the same materials currently disclosed for the purpose of a microbial attachment/biofilm synthesis inhibitor.

Nowhere is there a disclosure of a microbial attachment/biofilm synthesis inhibitor within the four corners of Solomon et al. This claim feature is simply missing and chlorhexidine, despite the Examiner's assertion, is not a microbial attachment/biofilm synthesis inhibitor. Since this claim element is missing, Solomon et al. fails to be an anticipatory reference.

For a reference to anticipate a claim it must disclose ***each and every elemen***t of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978)(emphasis added). Solomon et al. simply does not.

According to the final Office Action, "Applicant wrongly suggests that the claim 1 requires three components, since a single agent can be both an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor." Applicant respectfully disagrees.

First, as noted above, chlorhexidine is an antimicrobial agent, rather than a microbial attachment/biofilm synthesis inhibitor.

Moreover, even assuming for the sake of argument that chlorhexidine happened to be both an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor, such a single agent does not meet the language of claim 73.

"The words of a claim must be given their 'plain meaning' unless such meaning is inconsistent with the specification." See MPEP 2111.01.

In the present case the plain meaning of "a first annular layer comprising an extruded homogenous mixture of a matrix polymer, an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor" is that three distinct entities are present: (a) a matrix polymer, (b) an antimicrobial agent and (c) a microbial attachment/biofilm synthesis inhibitor.

The Examiner, on the other hand, is suggesting that applicant ignore the conjunction "and" in the claims. To give an everyday example, "an organic item, a household item and a kitchen item" would not be interpreted by an English-speaking person as being met by "an orange and a knife," due to the existence of the conjunction "and," which requires all three items. Similarly, a layer "comprising an extruded homogenous mixture of a matrix polymer, an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor" requires three materials: (a) a matrix polymer, (b) an antimicrobial agent and (c) a microbial attachment/biofilm synthesis inhibitor.

The specification is consistent with the plain meaning understanding that "an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor" must correspond to two different entities and cannot be met by a single entity.

Given that the Examiner has adopted a claim construction that is inconsistent with the plain meaning of the claims, it is respectfully submitted that such a claim construction is improper.

For at least the above reasons, claim 73, as well as claims 74, 84, 95, 97 and 103 depending therefrom, are patentable over Solomon under 35 U.S.C. 102(b).

Rejections Under 35 U.S.C. § 103(a) – Modak et al. in view of Solomon et al.

Claims 73-75, 80-90, 94-99 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al. in view of Solomon et al (U.S. Pat. No. 6,261,271). Applicant respectfully traverses this rejection.

In the Office Action, the Examiner argues that "Modak et al discloses a ureteral stent (col. 4, lines 16-36) comprising a polymeric tubular shaft having more than one layer (i.e. coating), said polymeric tubular shaft comprising a first annular layer comprising matrix polymer comprising, an antimicrobial agent (triclosan, title), and a microbial attachment/biofilm synthesis inhibitor (Ag EDTA, col4, lines 3-14)…"

As indicated in the Office Action, triclosan is an antimicrobial agent. Silver salts such as Ag EDTA, however, are *also* antimicrobial agents. See, e.g. the present specification at [0011]; see also Modak et al. at col. 1, lines 1-2 ("an antimicrobial other than a silver compound or triclosan").

The Office Action also urges that although Modak et al. remain silent as to using extrusion to prepare the tubing and agent resulting in a homogeneous bulk distribution, it "would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the extrusion method of Solomon et al in place of the dip coating method of Modak et al in order to [achieve] distribution of the agent in the base polymer. Such a modification amounts to mere substitution of one agent distribution method for another within the are [*sic*] of implantable tubing (ureteral stents)." Applicant respectfully disagrees.

First, dip coating is a room temperature process, whereas extrusion is an elevated temperature process, which is associated with various difficulties including agent degradation, among others.

Moreover, making the Examiner's proposed modifications to the device of Modak et al. would render the device unsatisfactory for its intended purpose.

Modak et al. is very clear that a solvent-based dip coating method is critical for success because of the inherent difficulties in creating medical articles with anti-infective coatings. Indeed, Modak et al. states:

> Successful treatment of a medical article with a polymer comprising an anti-infective agent may be ***problematic***, particularly where the medical article has a hydrophobic surface. The adherence of the polymer may depend upon (1) the

> polymeric matrix in which the anti-infective agent is suspended; (2) compatibility (or lack thereof) between the agent-polymeric matrix and the surface of the article; (3) the solvent system; and (4) the thickness of polymer/anti-infective agent desirably applied. Furthermore, ***the rates of release of various anti-infective agents from diverse polymers may differ***. To address these ***issues***, the present invention provides for two different methods for treating medical articles: one-step method, and a two-step method, both of which are set forth below.

Modak et al., col. 5, lines 52-65.

Modak et al. carefully details its one-step method and two-step method, both of which constitute detailed and extensive solvent-based solutions involving "coating, dipping or soaking the article in a treatment solution of a hydrophilic polymer" (col. 6, lines 20-21), "coating, dipping or soaking the article in a treatment solution of a hydrophobic polymer" (col. 6, lines 63-64), or "treat[ing] with a solution comprising one or more silver compounds, triclosan and/or other chlorinated phenol, and optionally containing a biomedical polymer, dissolved in one or more solvents, wherein the solvent(s) selected is (are) capable of swelling the polymeric medical article to be treated; such a solution is referred to herein as an "impregnating solution" (which is a species of treatment solution), and the process by which the article is treated with triclosan and a silver compound is referred to as "impregnation" (col. 7, line 67 to col. 8, line 9).

Relatedly, Modak et al. also make clear that an impregnation-based method is critical for success. In this regard see, e.g., the paragraph spanning cols. 2-3 of Modak et al. (emphasis added):

> The present invention is also based, at least in part, on the discovery that the surface of medical articles, especially catheters, ***impregnated*** with triclosan and silver compounds generally were found to be smoother and shinier in comparison with catheters impregnated with triclosan and chlorhexidine.... Without being bound by any particular theory, it is believed that medical articles of the invention, ***by virtue of their smooth surfaces***, may be less physically irritating than prior art devices, may be less likely to provoke fibrinogen and/or fibronectin deposition, and therefore may avoid bacterial colonization.

There is no evidence that such desired results could be achieved by extrusion and, given the fundamental differences between dipcoating and extrusion, such results would not be expected.

Given such teaching as the backdrop, one of skill in the art would not be motivated to dispense with the dip coating solutions of Modak et al. in favor of an extrusion method of Solomon et al. since such substitution would be in contravention of the teachings of Modak et al.

Further, one of ordinary skill in the art, given that Modak et al. teaches the "problematic" and complex nature of successfully creating a medical device using anti-infective agents (col. 5, lines 52-53), would not have a reasonable expectation of success that the claimed invention would result by such substitution.

Given the great differences between imbibing and extrusion techniques and given the disclosures of Modak et al. regarding the problems inherent in successful treatment of medical devices with polymers containing anti-infective agents, one of ordinary skill in the art would not find that the substitution of the dip coating method of Modak et al. with an extrusion method of Solomon et al. to be a "predictable solution" with a "reasonable expectation of success." Making this substitution would neither be "simple" nor would one of skilled in the art have a measure of confidence that the claimed invention would result.

For the reasons above, it is respectfully requested that the Examiner reconsider and withdraw the rejection of the claims.

Claims 76-79 and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al. and Solomon et al. and further in view of Schwarz, U.S. 2001/0022988.

These claims are patentable over Modak et al. and Solomon et al. for at least the reasons set forth above. Schwarz, which is cited for teachings concerning a stent using ethylene vinyl acetate copolymer for the purpose of holding drugs for local delivery, does not make up for these deficiencies.

Claims 100-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al. and Solomon et al. and further in view of Buscemi, U.S. 5,693,034.

These claims are patentable over Modak et al. and Solomon et al. for at least the reasons set forth above. Buscemi, which is cited for its teaching of a lubricant of hydrophilic polymer using polyacrylic acid for the purpose of lubricating medical devices, does not make up for these deficiencies.

Claims 102 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al. and Solomon et al. and further in view of Falk, U.S. 6,048,844.

These claims are patentable over Modak et al. and Solomon et al. for at least the reasons set forth above. Falk, which is cited for its teaching of a stent using ketorolac for the purpose of functioning as an anti-inflammatory agent, does not make up for these deficiencies.

Conclusion

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicants' attorney at (703) 433-0510 in order that any outstanding issues be resolved.

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